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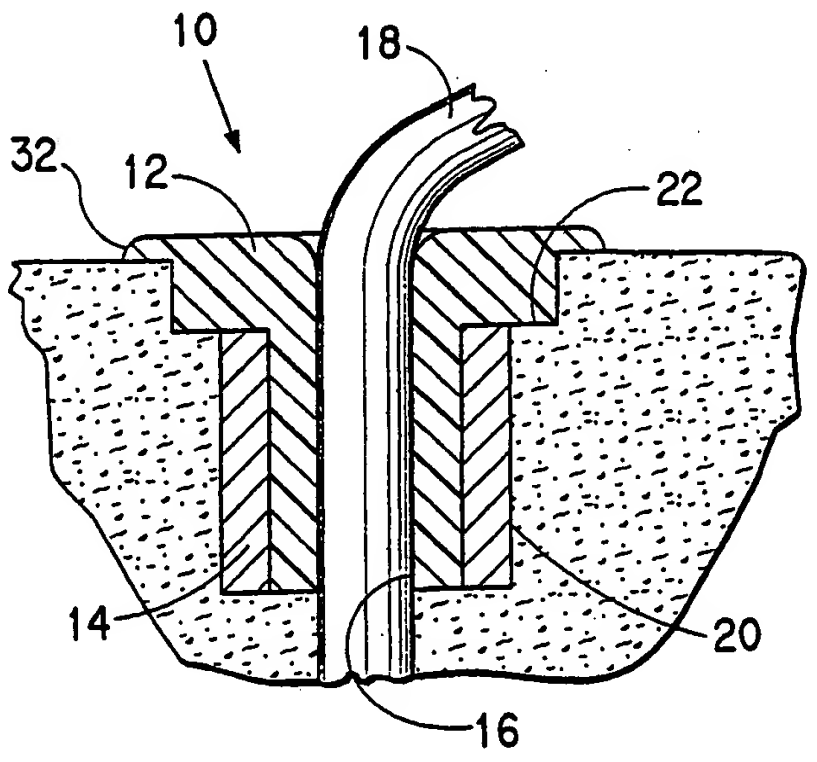

(57) Abstract

Novel prosthetic devices (10) are disclosed for positioning within a bone channel and receiving a ligament or a tendon (18). The device (10) comprises polymeric bearing means (12) having a longitudinal aperture (16) to receive a ligament or a tendon (18) therethrough, and metallic attachment means (14) securing the bearing means (12) within the bone channel. Further disclosed are processes for the preparation of the prosthetic devices (10) recited herein.

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Prosthetic device for ligament attachment and processes for the preparation thereof

FIELD OF THE INVENTION

This invention relates to prosthetic devices which are positioned within bone channels and receive ligaments or tendons therethrough. More particularly, this invention relates to prosthetic devices which protect ligaments or tendons from abrasion against skeletal surfaces, and processes for the preparation thereof.

BACKGROUND OF THE INVENTION

A variety of references are directed to the replacement in whole or in part of soft tissue structures, including ligaments and tendons. A recognized design goal is to provide prosthetic devices that closely model their natural counterparts, in form and function. For example, ligaments are frequently implicated in knee problems. A particularly problematic ligament is the anterior cruciate ligament (ACL), one of the ligaments which connects the femur and tibia across the knee. Research efforts respecting the replacement of ligament systems include the development of suitable synthetic materials used for the ligament itself, and acceptable attachment means to secure the ligament to various skeletal structures. Additionally, where ligaments and tendons are routed through bone channels, a design goal is to minimize abrasion of the ligament or tendon against the skeletal member.

W. C. Bruchman, C. W. Bolton, and J. R. Bain, in an article entitled "Design considerations for cruciate ligament prostheses" (as reported in "The Anterior Cruciate Deficient Knee, New Concepts in Ligament Repair" by D. W. Jackson and D. Drez, Jr. (C. V. Mosby

Co., 1987) review their involvement in the development of a prosthetic cruciate ligament. Several issues were presented therein relating to cruciate ligament substitution and fundamental criteria were reviewed for the assessment of the adequacy of a ligament prosthesis. The authors reported that after creep and flexural fatigue, the mechanical phenomena next most likely to cause failure of a prosthesis are abrasion and stresses at sharp edges. Abrasion (defined therein as wear produced through rubbing contact of surfaces) inevitably occurs when the prosthesis is routed through a narrow anterior intercondylar fossa. High-stress levels can occur at sharp edges (for example, osteophytes or the bone entry sites). In general, the response of natural or synthetic polymers is localized creep ("cold flow") at these areas. This is not abrasion, but can occur simultaneously with abrasion. The authors concluded that the effect is reduction in the load capacity of the prosthesis, potentially leading to failure.

Failure of anterior cruciate ligament prostheses was mentioned by the authors to be related to abrasion and stress concentration. These appeared to them to occur primarily in three areas:

1. The anterior rim of the femoral intra-articular bone entry site (when anatomical routing is employed)
2. The posterior rim of the entry site on the tibial plateau
3. The region of the intercondylar notch; an excessively narrow notch, osteophytes or other bony edges can impinge on the device; also, if the device exits the tibia anterior to the natural insertion of the anterior cruciate ligament, the notch

will be forced against the prosthesis in extension.

Another observation of Bruchman et al. was that materials that are more resistant to abrasion are also those that are harder. However they observed that bone loss through abrasion or high local compressive loads is a likely outcome with the use of hard polymer constructions.

U.S. 3,953,896 discloses a prosthetic ligament for replacing a natural ligament flexibly connecting two skeletal members together. The prosthetic ligament includes a bridge member for joining the skeletal members. The bridge member includes end portions for fixed attachment to the skeletal members and a flexible central portion. Nut members secure the bridge member to the skeletal members, while sleeve members protect the bridge member from abrasion as the skeletal members flex relative to each other. However, this device does not provide for a sleeve member including a rigid, metallic exterior structure fixedly secured to a bone channel.

PCT application US84/00770 discloses a barrier layer for implantable tendons and ligaments. A ligament substitute positioned within a channel of resected bone is interfaced with a sleeve of soft biological tissue. The sleeve extends through at least a portion of the channel and receives the ligament substitute therein. However, the barrier does not serve as a wear surface to minimize abrasion where the ligament or tendon contacts bone.

U.S. 4,776,851 discloses a prosthetic ligament with at least one intra-osseous bearing member in a bone joint and an intra-articular linkage means connecting the member to another bone to provide multiple degrees of freedom between the bones. U.S. 4,755,183 discloses

a prosthesis for an ACL featuring elongate members with separately tensionable cords. The prosthesis further includes catch means and means to secure the elongate members to the femur and tibia. However, these devices do not provide for a polymeric bearing means receiving a ligament or tendon therethrough together with a metallic attachment means securing the bearing means to the bone channel.

It is an object of the present invention to provide a prosthetic device which is positioned within a bone channel to permit extension and flexion of a ligament or tendon positioned therethrough with minimal abrasion. It is a further object of the present invention to provide a prosthetic device which is compact, minimizing the sacrifice of natural bone as it is positioned within the bone channel. A feature of the present invention is its curvilinear shaping where it bears upon the ligament or tendon, providing for smooth freedom of movement of the ligament or tendon upon the flexing of skeletal members. An advantage of the present invention is its durability. These and other objects, features, and advantages will become more readily apparent upon having reference to the following description of the invention.

SUMMARY OF THE INVENTION

The present invention provides for a prosthetic device positioned within a bone channel and receiving a ligament or a tendon therethrough. The device comprises polymeric bearing means having a longitudinal aperture to receive a ligament or a tendon therethrough, and metallic attachment means securing the bearing means within the bone channel. The device may be formed in a variety of shapes and configurations, such as having the bearing means received within the attachment means. A preferred embodiment features the bearing means and attachment means as substantially cylindrical and

further that the attachment means is positioned about the exterior periphery of the bearing means.

The prosthetic devices of the present invention may be prepared according to processes of the present invention. One such process comprises forming a polymeric bearing means having a longitudinal aperture to receive a ligament or a tendon therethrough; and, securing a metallic attachment means to the exterior periphery thereof.

BRIEF DESCRIPTION OF THE FIGURES

In the figures:

FIGURE 1A is a cross-sectional view of a prosthetic device according to the invention;

FIGURE 1B is a cross-sectional view of the prosthetic device of Figure 1A, secured within a bone channel and having a ligament or tendon incorporated therethrough;

FIGURE 2 is a side view in partial cross section of a prosthetic device according to the invention including radial projections to enhance frictional fit;

FIGURE 3A is a side view of the bearing means of a prosthetic device according to the invention including a plurality of longitudinal fingers;

FIGURE 3B is a cross-sectional view of a prosthetic device according to the invention including the bearing means of Figure 3A;

FIGURE 4A is a side view of a prosthetic device according to the invention including means of locating the device within a bone channel;

FIGURE 4B is a cross-sectional view at A-A of the prosthetic device of Figure 4A;

FIGURE 4C is a top view of the prosthetic device of Figure 4A;

FIGURE 5A is a side view of the partially assembled prosthetic device according to the invention as used in processes according to the invention;

FIGURE 5B is a side view of the assembled prosthetic device according to the invention, prepared according to processes of the invention; and

FIGURE 6 is a cross-sectional view of another prosthetic device according to the invention, and secured within a bone channel and having a ligament or tendon incorporated therethrough.

DETAILED DESCRIPTION OF THE INVENTION

Referring now with particularity to the figures herein, in Figures 1A and 1B the prosthetic device according to the invention is shown generally at 10. It comprises bearing means 12 and attachment means 14. Bearing means 12 has a longitudinal aperture 16 which receives ligament 18 therethrough. The device is placed within a channel 20 of bone, and attachment means 14 secures bearing means within the channel 20. Optionally and as illustrated in Figure 1B, bearing means 12 directly contacts the bone as at counterbore 22.

Figures 1A and 1B at 10 are illustrative of one variety of bearing means 12, and include certain features. In particular, the surface 28 which forms the length of the longitudinal aperture 16 is smooth. That is, the surface 28 is minimally abrasive to the ligament or tendon received therethrough. Further, the bearing means 12 is curvilinearly configured to minimize abrasion to the ligament or tendon so received. Thus and for example, at the location where the ligament extends out of Aperture 28 the bearing surface 12 is formed as a curve at 30. This ensures that as the ligament or tendon moves about this area, it is protected or shielded from the abrasive texture of the bone itself and contacts a smooth curved surface.

The bearing means 12 may also incorporate a flared portion 32. Flared portion 32 extends outside the perimeter of the attachment means. As depicted, the prosthetic device extends outside the external surface of the bone. Thus, the bearing means 12 including the curve 30 and flared portion 32 remain outside the bone. Alternatively, the prosthetic device may be installed so that it is flush with the external surface of the bone. Further as depicted, the outer contour of the prosthetic device forms several "steps"; here three steps are shown, as at the flare 32, at counterbone 22, and at the furthest inserted end of the device. It can be appreciated that other numbers of steps are included in this invention, as required for a design suitable for a particular need. It is to be further understood that the cross-sectional widths of the bearing means and attachment means may vary relative to each other. Thus, in Figure 1B, the maximum width of the bearing means 12 exceeds that of the attachment means 14; this permits the formation of the additional steps at flare 32 and counterbone 22. Another arrangement (with only one step, at the furthest inserted end of the device) contemplates the bearing means 12 and attachment means 14 being of equal cross sectional width.

The attachment means 14 may be designed to encourage tissue attachment to it, for example, by providing a substrate comprising pores in the range of 10 to 500 microns such that tissue ingrowth occurs. Alternatively to porosity or in addition to it, tissue fixation may be encouraged by incorporating calcium phosphate materials such as hydroxyapatite in attachment means 14, for example, by plasma spraying. Such biological fixation provides a strong long term bond between the attachment means 14 and, thus, device 10, and the bone in the adjacent channel 20. Since

biological fixation may take 3 months or longer to reach an adequate level for secure attachment, additional means are required to insure adequate short term fixation. For example, attachment means 14 may have a slightly larger diameter than channel 20 to provide a frictional, press fit. To further enhance this frictional fit, attachment means 14 may have a roughened exterior. Alternatively or additionally, frictional (or press fit) fixation may be enhanced by providing a plurality of projections extending radially from a portion of the bearing means 12 not covered by the attachment means 14. In Figure 2, a prosthetic device according to this embodiment is depicted generally at 10. Projections 24 extend outwardly from the bearing means 12. Thus, when the prosthetic device is inserted within a bone channel, both these projections 24 of the bearing means 12 and the attachment means 14 engage the channel.

A means according to the invention herein for providing fixation of bearing means to attachment means is depicted in Figures 3A and 3B. In Figure 3A, the prosthetic device is shown generally at 10 and illustrates only bearing means 12. The bearing means 12 is formed at one end of the device into a plurality of fingers 26. The fingers 26 extend radially therealong at the end of the device inserted within the attachment means 14. When inserted as in Figure 3B, the fingers 26 are compressed within the attachment means 14 so that the engagement is enhanced by the compressive forces exerted therein. The fingers 26 may include edge portions 27 to additionally secure the bearing means 12 to the attachment means 14 (such as a "snap fit" relation), as the attachment means 14 is disposed about the bearing means 12 between the edge 13 and edge portion 27.

Another embodiment of the present invention is shown in Figures 4A, 4B and 4C. The device shown generally at 10 comprises a bearing means 12 together with an attachment means 14. In addition, the bearing means 12 is curvilinearly configured as a slope or a bevel as at 33. When configured as a bevel, the bearing means 12 may be sloped at any desirable angle, from essentially 0° to 90° measured from the longitudinal axis thereof. Typically in order to match the curvature of the skeletal member at the mouth of the bone channel, bevels of 40-80° are utilized. In use, this particular design would occupy a bone channel, and further at the juncture of the device with the external edge portion of the bone the bevel is formed parallel to the plane of the bone surface. In other words, devices according to the invention can be contoured such that at the point where the ligament enters the channel of resected bone, the device is flush with the surface characteristics of the bone or slightly raised from the bone surface but parallel to it.

The prosthetic device herein can be advantageously be formed of a variety of materials. The design requirements are such that the bearing means 12 be constructed of any polymeric material capable of forming a smooth, curvilinear surface and further preferably that it have good wear resistance. Thus, certain varieties of polymers are particularly useful in forming the bearing means of the invention. Preferably the polymer is a polyethylene such as ultrahigh molecular weight polyethylene (UHMWPE); this polymer is prepared according to methods and using chemicals as is understood and readily appreciated by those skilled in the art. The design requirements are further such that the attachment means 14 be constructed of any metallic material capable of forming a rigid member to support

the bearing means 12. Thus, certain metals are particularly useful in forming attachment means 14 of the invention. Preferably the metal is either titanium or cobalt/chrome alloy. The present prosthetic device may be used with any natural or artificial ligament or tendon, and for any anatomical joint.

The prosthetic devices according to the invention may be prepared by processes according to the invention. As reviewed earlier herein, the attachment means is secured to the exterior periphery of the bearing means. In Figures 4A, 4B and 4C is further illustrated one such means of performing this attachment. In Figure 4C, the bearing means 12 has an aperture 37 and the attachment means 14 has a protruding portion 35 formed thereon. As an additional measure of attachment of the bearing means 12 to the attachment means 14, the aperture 37 and protruding portion 35 mate with each other in a secured fashion as best viewed in Figure 4B. Moreover, it is important to locate the prosthetic device within a bone channel so that the bevel or other curvilinear contour is desirably positioned to follow the configuration of the skeletal member at the exposed surface. To accomplish this precise orientation of the device within the bone channel, there is developed (as in Figures 4A and 4C) a cut out portion 34. A locator tool fits within the longitudinal aperture of the device and also includes a protruding surface which fits within the cut out portion 34 so that the orientation of the device relative to the locator tool is always understood as the device is installed within the resected bone channel.

In Figures 5A and 5B there is illustrated generally at 10 another prosthetic device according to the invention. The bearing means 12 (and prior to being secured to the attachment means 14) includes the portion 38. The attachment means 14 is placed over the portion

38 of the bearing means 12 until it abuts the edge 40. With the attachment means 14 abutting the edge 40, a portion of the bearing means 12 extends beyond the other end of the attachment means 14 as seen in Figure 7A. Thereafter, this portion is heat deformed to form a lip 42 as in Figure 5B which secures the attachment portion 14 to the bearing portion 12. A preferred structure according to the invention is depicted in Figure 6. This structure incorporated several of the features described herein, including the heat formed lip 42, the multiple steps as at 22, and the bevel. It can be appreciated that the present invention contemplates a wide variety of grommet which selectively incorporate various features disclosed herein as desired for a particular application. It can be further appreciated that a variety of other means to secure the bearing portion to the attachment portion are possible and are considered part of the invention herein.

The invention will be further understood upon having reference to the following example herein.

EXAMPLE

In this example, an attachment means which is a cylindrical sleeve of titanium alloy is machined according to techniques readily understood by those skilled in the art. A bearing means which is an insert for the attachment means is a high performance, high molecular weight polyethylene. The bearing means is machined to include flared portion 32, beveled contour and portion 38 according to techniques readily understood by those skilled in the art. The portion 38 is inserted into the attachment means until the bearing means abuts the attachment means at edge 40. As inserted, the portion 38 protrudes about 1.5 mm beyond the attachment means at the distal end.

A metal bar with a hemispherical shape on one end is heated to 250°F. Within 4-5 seconds after removal from the oven, it is pressed against the protruding end of the portion 38, at the back of the attachment means, for a duration of 15 seconds. This enlarges the opening at the back end of the attachment means and flares it. Then a flat stainless steel plate, likewise heated in a 250°F, is pressed against the flare for 15 seconds. This presses the flare at the back of the attachment means against the attachment means.

Claims:

1. A prosthetic device positioned within a bone channel and receiving a ligament or a tendon therethrough, the device comprising:

polymeric bearing means having a longitudinal aperture to receive a ligament or a tendon therethrough, and metallic attachment means securing said bearing means within the channel of resected bone.

2. The prosthetic device of Claim 1 wherein said bearing means and said attachment means are substantially cylindrical and said attachment means is positioned about the exterior periphery of said bearing means.

3. The prosthetic device of Claim 1 wherein said attachment means is secured within the bone channel by biological fixation.

4. The prosthetic device of Claim 3 wherein said attachment means has a porous exterior to enhance biological fixation.

5. The prosthetic device of Claim 3 wherein said attachment means comprises one or more calcium phosphate compounds to enhance biological fixation.

6. The prosthetic device of Claim 5 wherein said compound is hydroxyapatite.

7. The prosthetic device of Claim 3 wherein said attachment means has a porous exterior and additionally

comprises one or more calcium phosphate compounds to enhance biological fixation.

8. The prosthetic device of Claim 1 wherein said attachment means is secured within the bone channel by frictional fixation.

9. The prosthetic device of Claim 8 wherein said attachment means has an abrasive exterior to enhance frictional fixation.

10. The prosthetic device of Claim 1 wherein a portion of said bearing means and said attachment means engage the bone channel, said bearing means at the location of engagement including a plurality of projections extending radially therefrom.

11. The prosthetic device of Claim 2 wherein said bearing means comprises a plurality of fingers extending longitudinally therealong at the end inserted within the bone channel, said fingers frictionally engaging said attachment means.

12. The prosthetic device of Claim 1 wherein the surface of said bearing means is minimally abrasive to the ligament or tendon received therethrough.

13. The prosthetic device of Claim 1 wherein the shape of said bearing means is curvilinearly configured to minimize abrasion to the ligament or tendon received therethrough.

14. The prosthetic device of Claim 13 wherein the curvilinear configuration of said bearing means includes a flared portion extending outside the perimeter of said

attachment means and adjacent to the external edge portion of the bone channel.

15. The prosthetic device of Claim 1 wherein said bearing means and said attachment means are curvilinearly configured as the contour of the bone at the juncture of the prosthetic device with the external edge portion of the bone channel.

16. The prosthetic device of Claim 15 wherein the curvinlinear configuration is a bevel having a slope of from approximately 0° to 90° measured from the longitudinal axis of said bearing means.

17. The prosthetic device of Claim 16 wherein the bevel has a slope of from 40° to 80°.

18. The prosthetic device of Claim 1 wherein said bearing means is polyethylene.

19. The prosthetic device of Claim 1 wherein said attachment means is selected from the group consisting of titanium and cobalt/chrome alloy.

20. The prosthetic device of Claim 1 wherein the ligament or tendon comprises a rigid insert and a flexible insert within a sheath, said rigid insert disposed within the bone channel, said flexible insert disposed outside the bone channel, and said prosthetic device positioned between said inserts.

21. The prosthetic device of Claim 1 wherein said attachment means is secured within the bone channel by biological and frictional fixation.

22. The prosthetic device of Claim 1 wherein said polymeric bearing means is received within said metallic attachment means.

23. A process for the preparation of a prosthetic device positioned within a bone channel and receiving a ligament or a tendon therethrough, the process comprising:

forming a polymeric bearing means having a longitudinal aperture to receive a ligament or a tendon therethrough; and,

securing a metallic attachment means about the exterior periphery thereof.

24. The process of Claim 23 wherein said attachment means is secured to said bearing means by disposing said attachment means about the exterior periphery of said bearing means and melt forming said polymer about an end of said attachment means.

FIG.1a

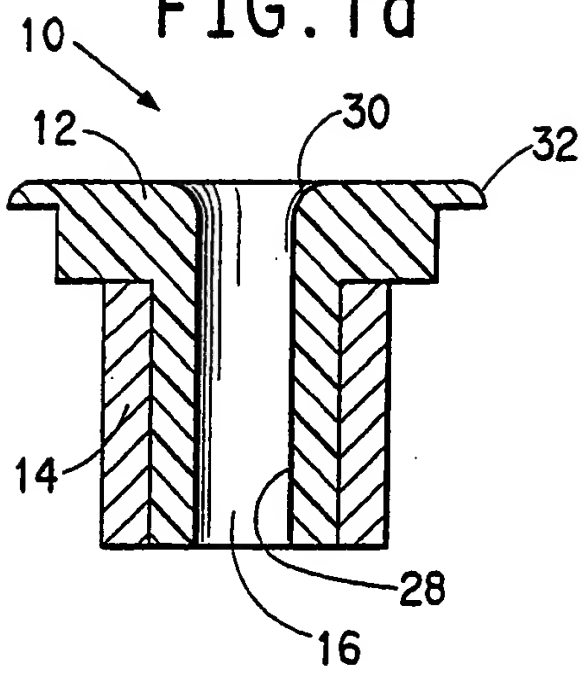


FIG.1b

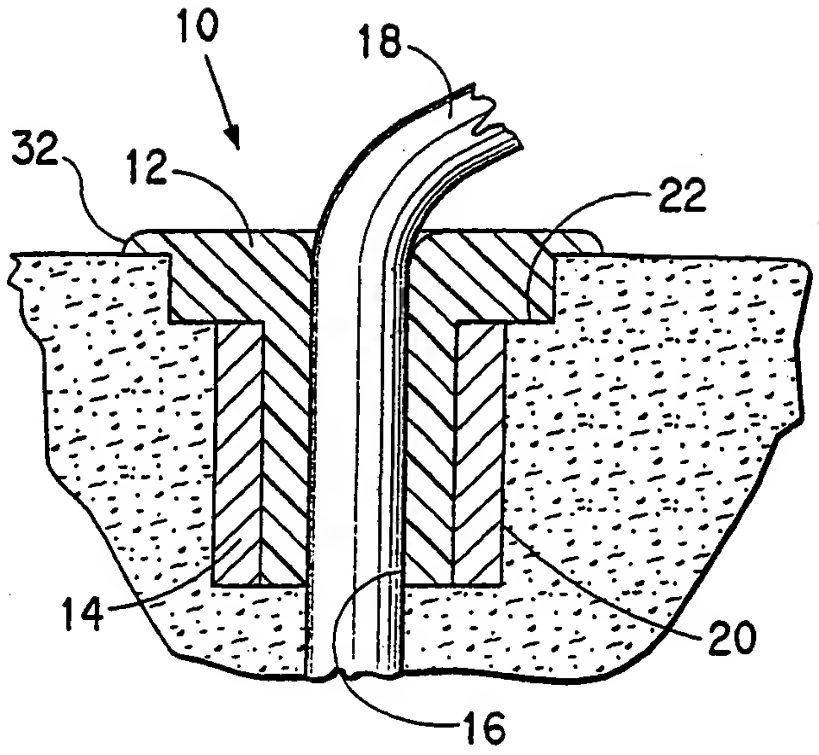


FIG.2

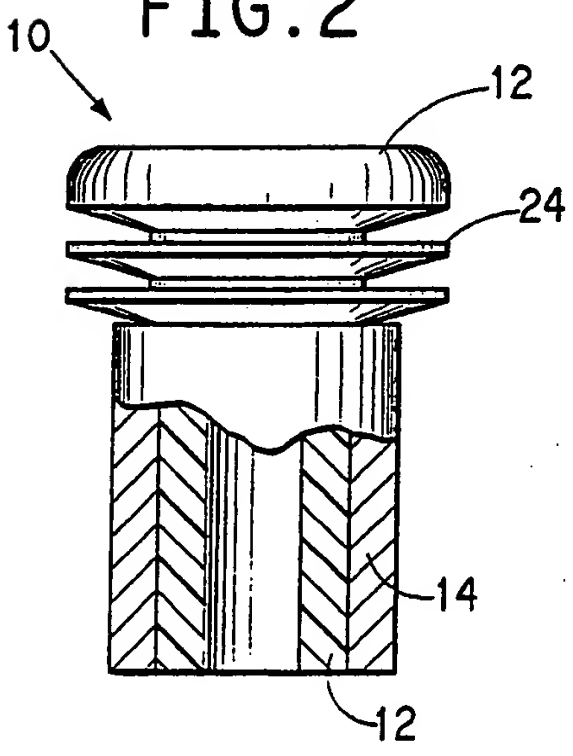


FIG.3a

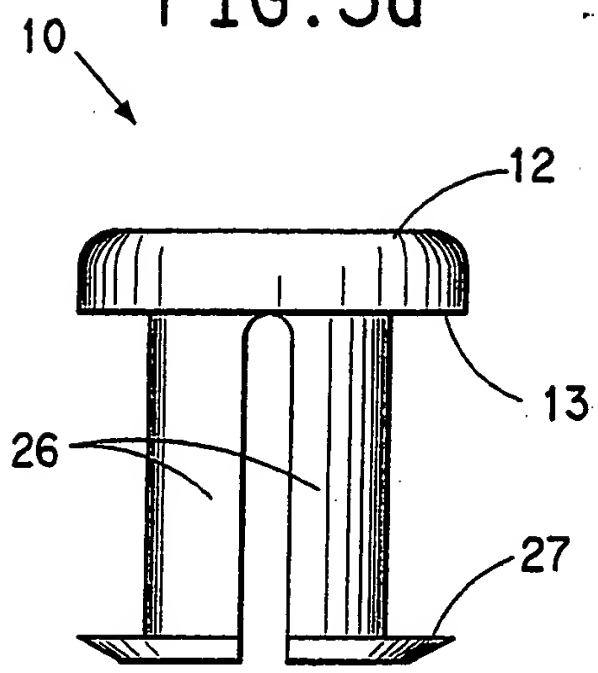


FIG.3b

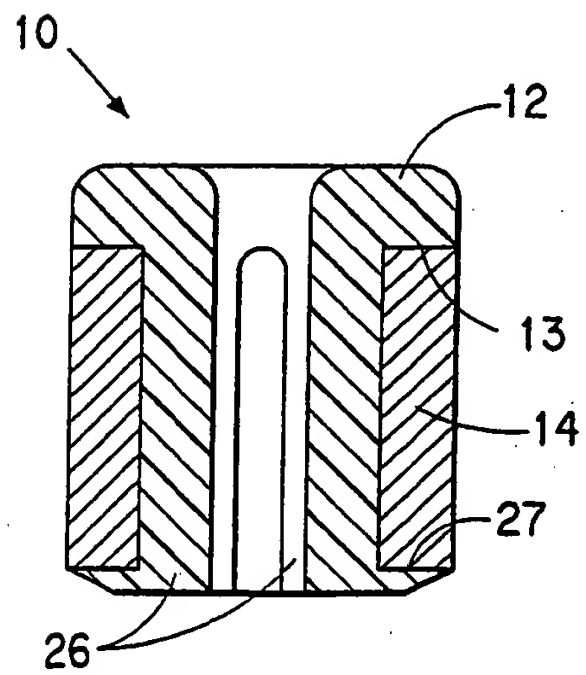


FIG.4c

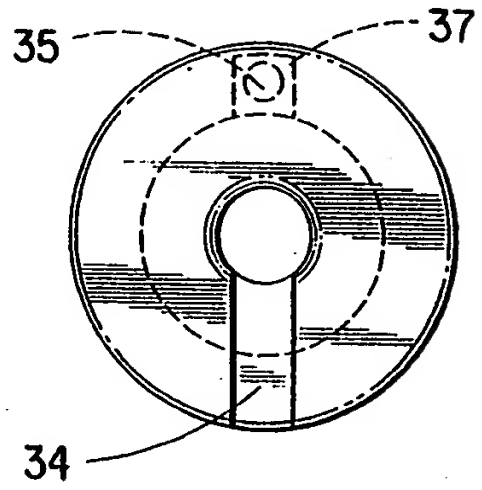


FIG.4a

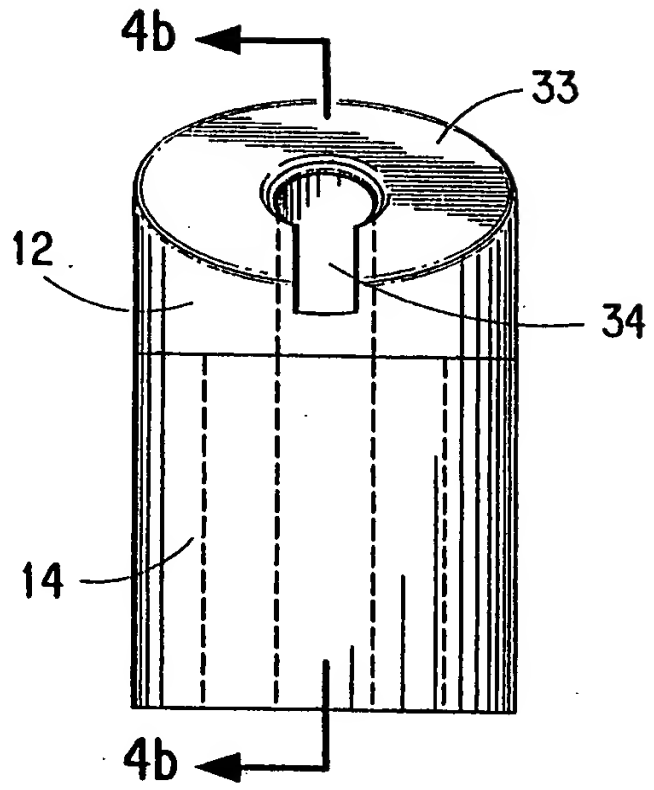
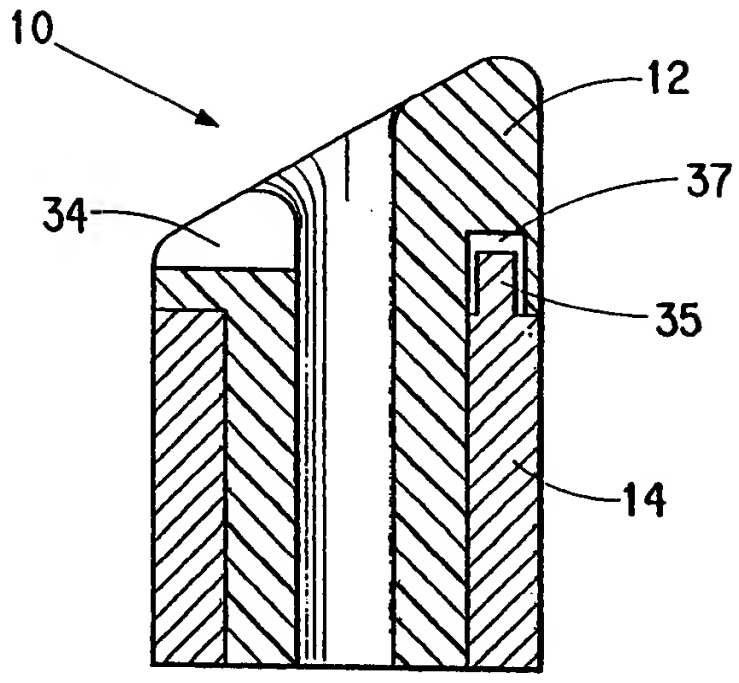


FIG.4b



PCT/US91/09060

FIG.5a

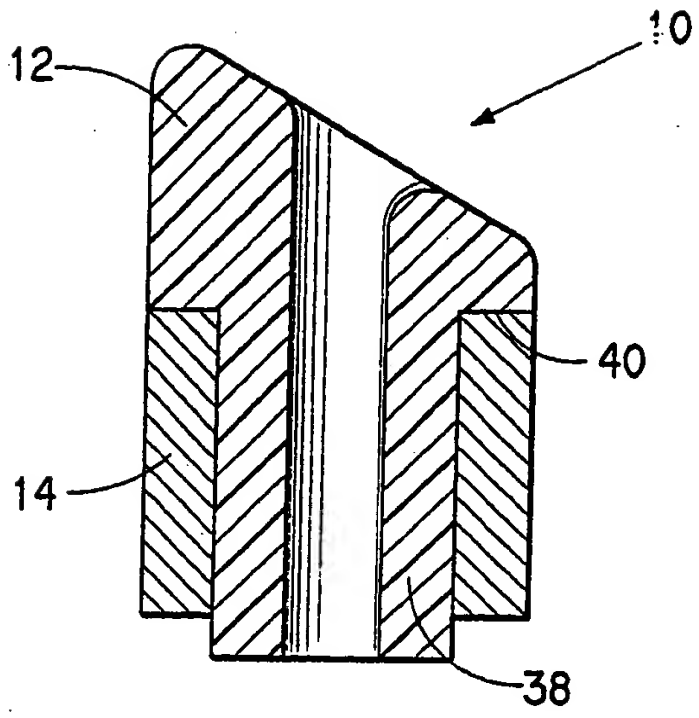


FIG.5b

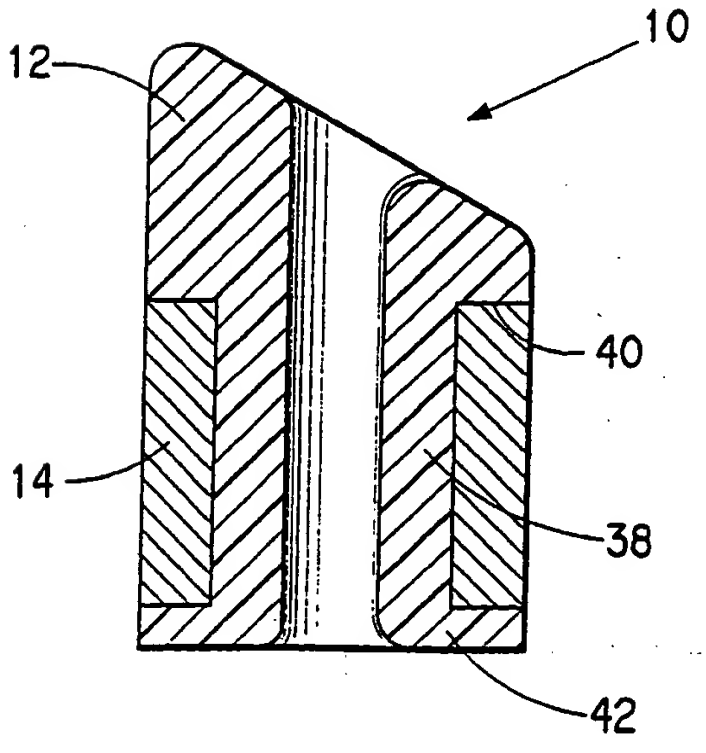
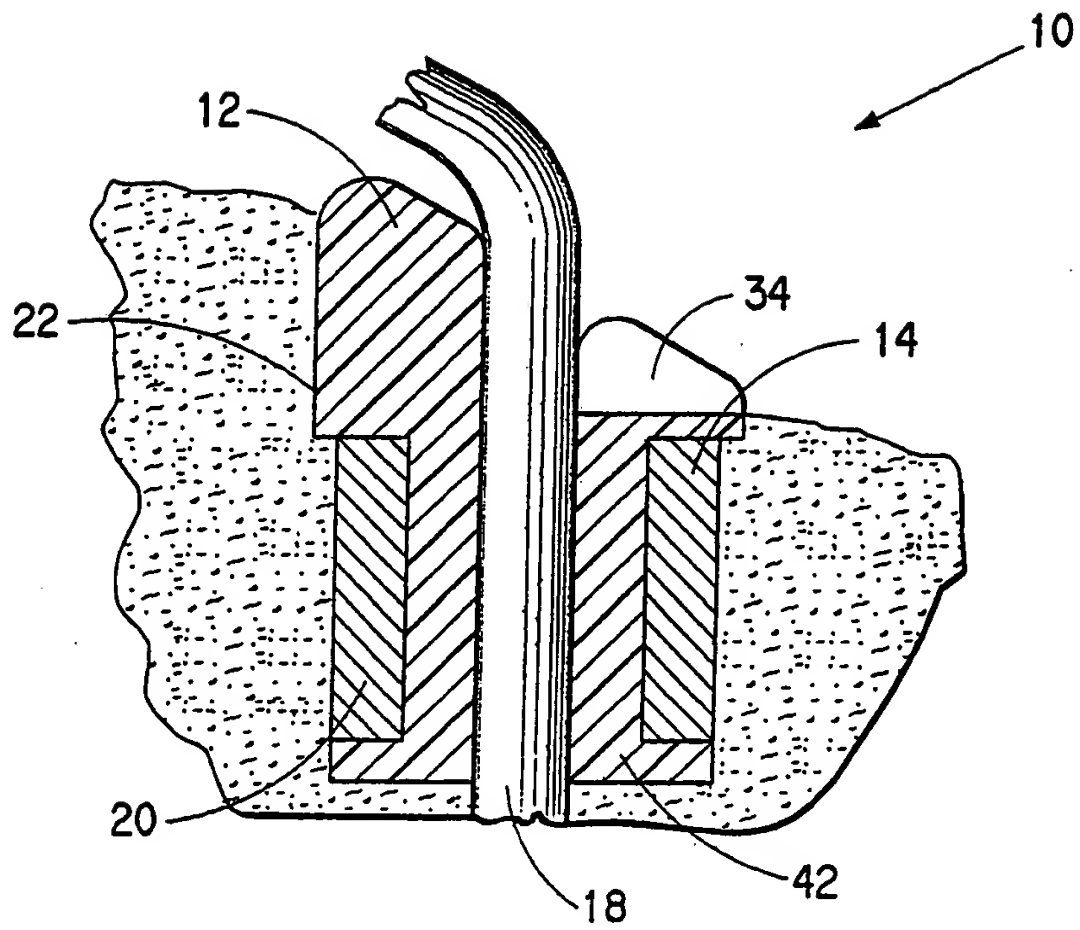


FIG.6



I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/08; A61F2/30

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category°	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	EP,A,0 260 787 (W.L. GORE & ASSOCIATES) 23 March 1988 cited in the application see column 4, line 38 - column 5, line 7; figures 5,6,10	1-4,8,9, 12-15, 19,21-24
Y	EP,A,0 232 049 (PFIZER HOSPITAL PRODUCTS GROUP) 12 August 1987 see page 8, line 1 - line 18; figures	1-4,8,9, 12-15, 19,21-24
A	FR,A,2 636 836 (AUGAGNEUR) 30 March 1990 see claim 1; figure 1	4-9,19
A	US,A,4 542 539 (ROWE ET AL.) 24 September 1985 see column 3, line 20 - line 25; claims 1-4	4,8,9,19

-/--

° Special categories of cited documents :[10]

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
03 APRIL 1992	21.04.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	GODOT T.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
P,A	WO,A,9 107 929 (BAXTER INTERNATIONAL) 13 June 1991 abstract see figures 7-9	1

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9109060 SA 55196

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The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 03/04/92

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82